**Detailed Script**

## Slide 1: Intro slide

**Speaker: Taylor Gillespie**

Hi, I'm **Taylor Gillespie** from the U.S. Environmental Protection Agency. I want to thank you for taking time out of your busy lives to be here tonight.

## Slide 2: Technical Help

**Speaker: Taylor Gillespie**

If you are having any trouble, please reach out using the Q/A feature. You can find the Q/A feature on the bottom of your screen. We are going to give folks another minute or two to join or move rooms and then we will get started.

For the folks that are just now joining us, I'm **Taylor Gillespie** from the U.S. Environmental Protection Agency and I'm the moderator for tonight's call. We are here tonight because our mission at EPA is to protect human health and the environment, and we are concerned about health risks from a specific source of air pollution in America.

I want to share a couple things about myself before we get started tonight. I want you to know two things about me which I believe will tell you more about how I will moderate this meeting than just sharing my job title here at EPA. The first, is that I grew up in a very small town with parents who were a teacher and a nurse and part of the heart of that town, so I really understand the importance of protecting and empowering communities with risk information. The second is that I am an Army Veteran. I hope to use skills from my experience and background to show you the respect and empathy you deserve but also to keep us on target, and to make sure your questions are answered and that we communicate clearly about what we know and how we are working to address it. **This may mean asking you to clarify your questions in the module or asking our speakers to readdress something I feel that it is unclear.**

For several reasons that my colleagues will describe this is a tough issue to communicate and so I want to acknowledge that this is not an easy conversation we are going to have tonight. We are going to answer questions at various points throughout the webinar so please type your questions into the Q/A module whenever they come up. We will either work to answer you directly or answer your question out loud. If we don't get to your question, please know you can email us at [ HYPERLINK "mailto:eto@epa.gov" \h ].

Now I would like to introduce you to my colleague, Madeline Beal, who will talk to you about EtO, its uses, and risk.

## Slide 3: Why we are here today

**Speaker: Madeline Beal**

I'm **Madeline Beal** and I work for the United States Environmental Protection Agency. I want to thank you for taking time out of your busy lives to be with us to learn more about this issue. We are here because our mission at EPA is to protect human health and the environment, and we are concerned about health risks from a specific chemical used by the B. Braun Facility in Allentown.

I understand that this presentation might be upsetting or frustrating. While I work for EPA, I am also a mom of four young children, and I approach my life including my work as a mom first. That means that I have thought a lot about how it would feel to be in the audience tonight to learn there might be a risk in my community or a risk to my family and I just want to validate that it is totally reasonable if you feel scared or upset or angry at this.

Before we get into the details, I want to first share (from my perspective) what the 3 main takeaways are tonight.

- First, risk in communities near a number of commercial sterilizers is too high. EPA is concerned about this risk.
- Second, we are committed to protecting health in communities facing risk from ethylene oxide and we are taking this issue seriously. I commit to you today that we will continue to work on this issue until the risk levels are reduced. This includes using the tools we have available to us at EPA, such as regulations and on the ground partnerships with states, communities, facilities, and anyone who can work with us to help reduce the risk. **These partnerships have already reduced risk in a number of communities, but we need to do more.**

## Slide 4: Website/Email

**Speaker: Madeline Beal**

- Third, you deserve to be a part of this process, to have your voices heard, your concerns shared, and your needs met. We will share more information about this later on the call, but you can also find more details about everything we will talk about tonight -- including how to make your voice heard -- on EPA's website at the link we are putting on the slide now.

## Slide 5: What is EtO

**Speaker: Madeline Beal**

You've already heard that we are talking about air pollution from a chemical called ethylene oxide, which we often refer to as EtO.

Occasionally people call this EO as well so if you see EtO, EO or Ethylene Oxide, it is all taking about the exact same chemical. You usually can't smell or see EtO in the amounts we find in the air near facilities or in communities.

## Slide 6: EtO Uses

**Speaker: Madeline Beal**

EtO is used to kill bacteria and other germs. Specifically, it is used to sterilize medical equipment and spices. While it is also used in other ways like making antifreeze or plastic bottles, tonight we are here

to talk about risk from EtO used to sterilize things at specialized facilities. These facilities are called commercial sterilizers.

## Slide 7: No indication of risk

**Speaker: Madeline Beal**

**EtO comes out of these facilities as air pollution only.** We have no information to suggest that EtO is coming out into the water or onto the ground in any way that would cause risk.
When it comes to short term health benchmarks, we haven't seen any evidence that EtO near these facilities causes urgent or acute health issues like nausea, dizziness, and breathing problems. This is an important point, the science we have done only points to risks from a long-term exposure based on our best current knowledge of what is happening at these facilities.

Generally, you as a consumer, don't need to be concerned about risk from EtO that might be left over on products that were sterilized with EtO, whether those are medical products or spices. Again, the risk we are concerned about is to people who live near and work at these facilities.

So if these are the things that we aren't worried about, what are we worried about?

## Slide 8: Over your lifetime

**Speaker: Madeline Beal**

What we've learned, is that EtO can cause cancer when people are exposed over long periods of time. Specifically, it can cause breast and lymph or blood cancers. By long periods we mean when people who live near one of these facilities breathe EtO every single day from birth until age 70.

## Slide 9: Special Considerations about Risk

**Speaker: Madeline Beal**

Certain people are more at risk from EtO. This can happen either because they spend more of their time in areas where there is a lot of EtO, like might occur in workers who work at these facilities or it can happen because, for some reason, their bodies are more susceptible. Children and babies are more vulnerable to EtO exposure. My colleague will talk more about this in a moment, but because we know children are more vulnerable, we explicitly consider that in our analysis.

## Slide 10: National Context

**Speaker: Madeline Beal**

Now I want to provide a little more national context.
There are about 100 of these commercial sterilizers in the country. You can see where they are located on the map here. The blue dots show the locations of the 23 sterilizers where we anticipate risk to be the highest for the people who live nearby.

We are focusing the conversation today on the facilities where we believe there is the highest risk to people who live nearby, but I want to be clear that there is also potential risk to people who work in

these facilities or who work or go to school nearby. We are considering all the almost 100 sterilizers when we think about these issues and propose solutions in our regulations.

The information we are sharing tonight and that we have posted on the web is all based on information we have collected from these facilities about their use of EtO. If EPA receives new data, we may update this information. We are continuing to collect and verify information about these facilities and if we learn and are able to verify important steps that they have taken to reduce risk, we will share that information on the webpage for that facility.

Many facilities are already taking action to reduce eto pollution and many others are planning to do more to reduce it.

While we are concerned about risk in these communities, EtO is not a chemical that lasts for a long time in the environment. This means that reducing the EtO coming out of the facility will reduce risk right away.

## Slide 11: Understanding Risk

**Speaker: Madeline Beal**

If you want to understand your family's risk, there are three things to know:

- how close are you to the facility?
- how much EtO is coming out of the facility?
- how long have you been exposed, both in terms of years in your neighborhood and hours each day that you are near the facility?

## Slide 12: How long are people exposed?

**Speaker: Madeline Beal**

To estimate risk from a given chemical, we need to how toxic the chemical is, how much there is in the air, and how long throughout a person's life someone might be exposed to it. EPA's analysis needs to be protective of health, so we use estimates of how long people are exposed that are on the extremely high end. For exposure to EtO, we are talking about people who live nearby one of these facilities. We assume that people spend all of their time in the area where there is risk – specifically, we assume exposure for 24 hours a day, 7 days a week, from birth to age 70 breathing in EtO in the area where there is risk. Those might not be realistic assumptions, but they do ensure that we are being protective of public health for everyone – even in that most extreme situation.

We used this information to assess risk for every commercial sterilizer in the country.

## Slide 13: Reducing EtO coming out of facility is best way to reduce risk

**Speaker: Madeline Beal**

## Slide 14: Where EtO Comes from at the Facility

**Speaker: Madeline Beal**

## Slide 15: Details about this analysis

**Speaker: Madeline Beal**

While this completed analysis of exactly where risk is, is recent, we have been working on EtO at EPA for much longer. This slide shares some of the key points on that work.

We have had regulations in place on EtO emissions for 30 years. In 2016, because of updated science, we learned that EtO was more dangerous when you breathe it in.

In 2018 a national level analysis provided an initial indication of which areas might have higher risk, but it wasn't detailed enough either to inform our regulation or to really help communities. We needed to collect additional data to learn much more exactly where that risk is and what the solutions are to prevent the risk. That work took about two years and brings us to where we are today.

I also want to note that while we very recently came to know exactly which communities were still facing higher risks based on current facility operations, the risk has potentially been occurring in some of these communities for as long as these facilities have been operating. To be clear, our risk estimates represent current – not historical – conditions because that is the best and, in some cases, the only information we have. It is also the information we need to set regulations going forward.

## Slide 16: B. Braun, Allentown, PA

**Speaker: Madeline Beal**

B. Braun was originally one of the higher risk facilities in Region 3. However, the Pennsylvania Department of Environmental Protection (PADEP) has been working with the facility and controls were installed in 2020 which significantly decreased risk from the original estimates.

This map shows you the original results of the analysis we did for the community of Allentown, Pennsylvania as of late July.

Please keep in mind that these risk levels do not represent the current risk results which are well below 100-in-a-million.

This map is here because we were not able to create a new isopleth map AND to give you a spatial perspective – that is, risk is depended on how close you are to the facility.

I want to point out a few features on the map:

- The dark yellow box is the facility itself.
- The light-yellow area is a non-residential area near the facility where risks are high.
- And the blue area includes areas where risks are now reduced to below 100-in-1-million

In the blue shaded area, the risks, are below 100-in-1-million. As you move away from the facility, the risks get lower. I want to note that there is some uncertainty in these estimates as both operations at the facility and weather can change, but these are the best health-protective estimates we have available.

We use 100-in-1-million as our benchmark for identifying whether risk levels are considered "higher" and are of concern to EPA. When we say, 100/million we are saying that we estimate EtO exposure could contribute to an increase of 100 cancer cases if a million people were exposed at that level 24 hours a day, 7 days a week, from birth to age 70. We start our calculations at birth because we want to make sure we are protective of children. We use 1 million as the baseline for how we calculate risk but nowhere near that number of people live near this facility. Near this sterilization facility, there are a little more than 400 people living nearby the facility and the risk in this area is now reduced below 100-in-1-million.

Under the Clean Air Act, we focus on risks where people live. We are also concerned about risks to workers or others who might spend part of their time in the light yellow or non-residential area and in the facility itself, but this analysis was not focused on them. I will talk a little more about actions we are taking to address risk for workers and others who spend their time in these non-residential areas near facilities in a moment.

I want to remind you that while we are showing this map for Allentown, PA, the facility is working with PADEP to provide additional data that would confirm a reduction of risk in this community. EPA provides status reports for B. Braun which can be found on EPA's webpage that you see listed on this slide (Slide 16).

Our regulations will work to protect people who live near, work in, and work or go to school near all of the commercial sterilization facilities even if they are not one of the 23.

## Slide 17: Timeline

**Speaker: Madeline Beal**

## Slide 18: We do not believe there to be short-term or acute risks...

**Speaker: Madeline Beal**

## Slide 19: Risk – Recent Steps / Previous Work

**Speaker: Madeline Beal**

## Slide 20: Work in Progress.

**Speaker: Madeline Beal**

## Slide 21: For Updates and to Learn More.

**Speaker: Madeline Beal**

## Slide 22: Timeline.

**Speaker: Madeline Beal**

EPA expects to propose an updated air pollution regulation later this year. At that time, there will be a public comment period and a public hearing will be scheduled. The public comment period for a major air pollution regulation like this one is typically 60-90 days. Regulations often take about a year to become final once the public comment period closes. Once a regulation is final, under the Clean Air Act facilities typically have up to 3 years to comply with the regulation.

## Slide 23: Timeline (continued).

**Speaker: Madeline Beal**

I mentioned before that we are also concerned about risks to workers in these facilities and to people who work or go to school near them. EPA is also working on this under another federal law and intend to take that action along with our updated air rule.

First, we plan to release new information about risks for people who work with EtO as a part of their jobs, and for people who work or go to school near EtO facilities. Based on an analysis EPA released in 2020, we already know that the risks for workers in EtO facilities are too high. We hope that later this year, we will have a better understanding of these risks to share with you.

Second, we'll propose new limits on how EtO can be used within facilities. EPA's authority to do this comes from a law on pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act, or "FIFRA". EtO is considered a pesticide under federal law because it can be used to kill viruses and bacteria.

These new limits are intended to reduce risk to workers and to create additional protections for people who live, work, and go to school near EtO facilities. After EPA releases on this proposed pesticides decision, we will take comments from the public for at least 60 days. In most cases, it takes one to two years for pesticide labels, which define the terms of use, to be updated and take effect once they are final. It may take several years for facilities to make some changes, including changes that require building new infrastructure.

EPA expects that its forthcoming protections under the Clean Air Act and the Federal Insecticide, Fungicide, and Rodenticide Act will reduce risk for all who are exposed to EtO from these facilities.

I also want to talk about accountability. As we mentioned at the outset, our job is to protect human and environmental health. We do this by relying on the most current scientific knowledge to develop effective regulations, by holding facilities accountable to these regulations through enforcement, and by communicating clearly with you about our work and the knowledge we gain through this work. As our EPA Deputy Administrator said earlier tonight, we are committing to continue to work on this issue until the risk levels are reduced.

## Slide 24: Key Points.

**Speaker: Madeline Beal**

## Slide 25: How to find this information.

**Speaker: Madeline Beal**

## Slide 26: Next Steps.

**Speaker: Madeline Beal**

## Slide 27: Q&A.

**Speaker: Madeline Beal**

We are going to do our best to get through as many of your questions as we can. At the end of the night, if we didn't get to your question or you feel we did not answer it fully, please contact us as [ HYPERLINK "mailto:eto@epa.gov" \h ] and we will do our best to answer your question via email.

With that, the first question seems best for…